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(19)

(54) IMPROVEMENTS RELATING TO REPLACEMENTS FOR LIGAMENTS AND TENDONS

(71) We, THE WELSH NATIONAL SCHOOL OF MEDICINE, of Heath Park, Cardiff, Glamorgan, a British Body Corporate, do hereby declare the invention, for which we pray that a Patent may be granted to us, and the method by which it is to be performed to be particularly described in and by the following statement:—

It is well-known to replace damaged ligaments and tendons by means of artificial replacement elements, many of which have been formed of synthetic plastic material. Existing elements, however, suffer from various disadvantages and in particular they tend to break down over a period of time, and also present problems in anchorage, and in some cases have undesirable effects on local tissues.

From one aspect the present invention consists in a prosthesis or replacement element for a tendon or ligament comprising a plurality of individual fine flexible carbon fibres, which are inter-woven, inter-twined, or otherwise held together in a generally parallel arrangement, to constitute a coherent multi-fibre cord, and including means at the ends of the cord to prevent the cord unravelling at the ends, the arrangement being such that fresh tissue can penetrate between the fibres along substantially the length of the cord.

Preferably the fibres are of substantially pure carbon, exceeding 97% purity. For example they may be of the type sold under the Registered Trade Mark "Grafil" produced by Courtaulds Limited, Carbon Fibres Unit, and more particularly type Grafil A, being "high strain". The Grafil A high strain carbon fibre is specially prepared, is non-surface treated and non-resinated in such a way that the final carbon product is practically 100% pure. Such fibres are fundamentally distinguished from organic fibres which may be interwoven and carbonised in situ.

The ends of the fibres may be held together to prevent unravelling by further fibres or they may be grasped in a solid end element. The end fitting may be a cement or adhesive which is moulded into a point.

The invention is based on the surprising discovery that a prosthesis or replacement element formed in this way of multiple fine carbon fibres, interwoven or intertwined or otherwise held together, not only has excellent mechanical qualities and a long life with minimal harmful effects on the body but also, for reasons not clearly understood, encourages the formation of fresh tissue along and around the carbon fibres themselves. This fresh tissue may, in fact, penetrate between the fibres and eventually form what is in effect a reconstituted natural ligament, an effect which has hitherto never been achieved in ligament replacements. The fact that new tendons or ligaments may be induced to form along the length and throughout the carbon matrix represents a fundamentally different concept in ligament and tendon replacement. All other replacements available take the place of the absent tendon or ligament whereas this type of replacement actually encourages a new ligament or tendon to form.

The invention is particularly applicable to and of advantage in prostheses for human beings, where the expected long life and natural reconstitution of the tendon or ligament is of great value.

The invention may be performed in various ways and several embodiments will now be described by way of example with reference to the accompanying drawings in which:—

Figure 1 is a somewhat diagrammatic plan view of a sealed plastics envelope containing a prepared carbon fibre cord with moulded end points, in accordance with the invention,

Figure 2 is a side view on an enlarged scale illustrating one end of such a carbon fibre cord embedded in a moulded end fitting,

Figure 3 is a diagrammatic side view illustrating an alternative form of replacement tendon in which the carbon fibres are plaited,

Figure 4 illustrates another embodiment in which the carbon fibres are generally parallel and loose, but are held together at

intervals by fibre bands,

Figure 5 is a side elevation illustrating a replacement tendon according to the invention when in position joining muscular tissue to a bone, and

Figure 6 is an end view partly in section of the prosthesis of Figure 5.

In these examples the replacement ligament or tendon is formed initially from very fine carbon fibre tow which may contain approximately 10,000 individual parallel non-interwoven fibres or filaments. When the fibres are pressed together the strand may be of the order of 3 × 1 mm in transverse dimensions and the length of each strand may be between 50 and 100 cm. These fibres are preferably of the type sold by Courtaulds Limited from their Carbon Fibres Unit, Coventry, under the trade name "Grafil A", this being a high strain form of carbon fibre as opposed to the other usual types "high modular strength (HMS)" and "high tensile strength (HTS)". The fibres of this type have no surface coating and are not surface treated. They are entirely, or almost entirely, inert which is an extremely valuable property when located in the human body.

In the first example illustrated in Figures 1 and 2 three of four strands 10 each containing between 4,000 and 10,000 parallel carbon fibres are spun and counter-twisted to form multi-strand rope or cord 11 which is approximataly 5 mm × 2 mm in cross-section, and may be 100 cm in length. This is particularly convenient for many human ligament prosthesis applications, but it will be appreciated that to form larger or smaller ligaments any required number of filaments and strands may be used, which can be interwoven or intertwined, e.g. spun, twisted, plaited, or braided, or otherwise held together, as required. Excessive twisting, plaiting or braiding may be a disadvantage however, since it may introduce an excessive longitudinal "elasticity" which may not be desirable in all instances. On the other hand, a certain degree of twisting, plaiting or braiding is of value in providing a coherent non-elastic fibre form with satisfactory handling characteristics.

It is, of course, important that the twisted, plaited, braided or otherwise intertwined strands should be completely sterile and hygienic and the twisting, braiding or other operation is preferably carried out automatically on a suitable machine under sterile conditions.

The ends of each rope or strand are held together to prevent unravelling and also to assist in threading the rope through a small aperture for instance in bone or tissue.

Figure 2 illustrates how an end of the multi strand rope is embedded into a moulded pointed element 12 which may be formed of any suitable mouldable material. This is preferably adhesive and easily moulded and of a material which can be sterilised with the carbon fibres. Methyl Methacrylate, which is a normal cement used in surgery can be used, or for example an epoxy resin. In most instances the end element will be cut from the cord and removed after the prosthesis has been introduced into position. It is not always necessary therefore that the fitting should be inert and in all ways suitable for permanent implant in the body. If it is desired that the end piece should remain in position in the body with the prosthesis then, of course, it should be of a suitable material such as one of the two examples given above, or pure solid carbon.

Figure 3 illustrates another example in which the carbon fibre rope or cord 13 comprises three plaited strands 14, 15, 16, each formed of a large number of parallel carbon fibres, as in the previous example. In this example the ends of the plaited cord are bound by extra carbon fibre strands or sutures 17.

Figure 4 illustrates another embodiment in which the whole prosthesis is formed of parallel carbon fibres 18 held together at intervals by carbon fibre sutures 19 and gripped at the ends by pointed end fittings 20 which may be similar to the fitting 12 of Figure 2.

In an actual surgical operation, to introduce a replacement ligament as illustrated for example in Figures 5 and 6, one end of the prosthesis ligament 25 is passed through a small hole 26 drilled in the bone 27, and both ends are pulled through incisions formed in the muscle 28, turned back on themselves, knotted and held with three or four stout silk sutures. Instead of looping the prosthesis through a hole in the bone a small plug of bone cement such as Methyl Methacrylate, may be formed around the end of the carbon fibre strand and simply pushed into the formed hole in the bone. This may act only as a temporary anchorage until fibrous tissue growth has occurred into the interstices of the carbon fibres.

These prosthesis ligaments may be used for a variety of surgical purposes, including replacement and reinforcement of ligaments and tendons (excluding those in which a synovial sheath is involved), also for medial and lateral collateral ligaments of knee, and similar ligaments at ankle, elbow, and shoulder. It will have value in reinforcement of both soft and hard tissues about the hip, particularly in the case of dislocating hip prostheses. It may have a use as a cruciate ligament replacement in the knee, and may also have value in incisional hernia repair, and uterine and rectal prolapse.

Replacement ligaments and tendons according to the invention may be applied to veterinary procedures for animals, but are of particular value for human surgical purposes. Conveniently each prosthesis ligament is sterilised and packed in a sterile sealed envelope 30, as shown in Figure 1, together with a sterile thin wire hair-pin loop 31 to be used as a threader for passing the ligament through a small opening.

WHAT WE CLAIM IS:

1. A prosthesis or replacement element for a tendon or ligament comprising a plurality of individual fine flexible carbon fibres, which are interwoven, intertwined, or otherwise held together in a generally parallel arrangement, to constitute a coherent multi-fibre cord, and including means at the ends of the cord to prevent the cord unravelling at the ends, the arrangement being such that fresh tissue can penetrate between the fibres along substantially the length of the cord.

2. A prosthesis according to claim 1, in which the fibres are of substantially pure carbon.

3. A prosthesis according to claim 2, in which the fibres are of carbon exceeding 97% purity.

4. A prosthesis according to any of the preceding claims, in which the fibres are non-surface treated and non-resinated.

5. A prosthesis according to any of the preceding claims, in which the ends of the fibres are embedded or grasped in a solid end element.

6. A prosthesis according to claim 5, in which the end element is a moulded pointed end fitting formed of carbon or of an adhesive or cement such as methyl methacrylate.

7. A prosthesis according to any of the preceding claims, the arrangement of the fibres being such that the cord has negligible elasticity or expansion under tension other than that of the fibres themselves.

8. A prosthesis or replacement element according to any of the preceding claims, in which the cord comprises a plurality of strands each comprising a twisted tow of several thousand fine carbon filaments.

9. A package comprising a sterile sealed envelope containing a prostheis according to any of the preceding claims.

10. A package according to claim 9, including a threader for use in passing an end of the prosthesis through a small opening.

11. A prosthesis or replacement element for a tendon or ligament substantially in any of the forms described herein with reference to the accompanying drawings.

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Sheet 1

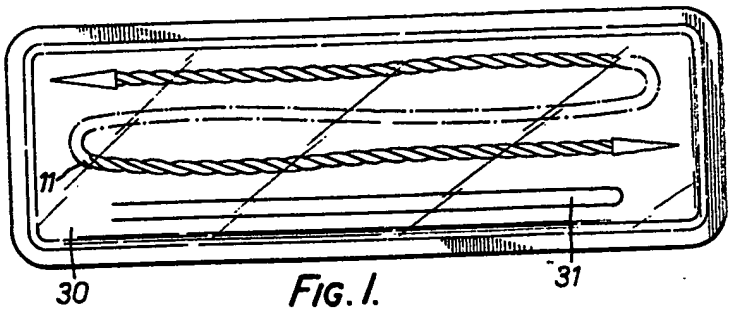

FIG. 1.

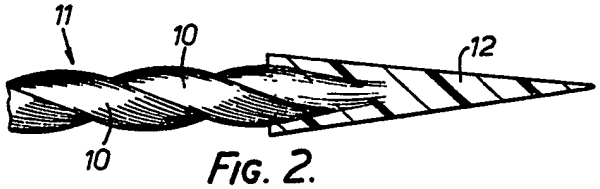

FIG. 2.

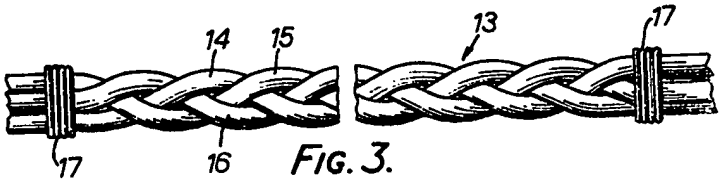

FIG. 3.

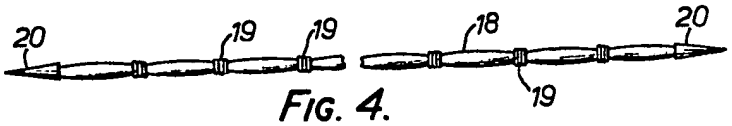

FIG. 4.

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2 SHEETS *This drawing is a reproduction of the Original on a reduced scale*
Sheet 2

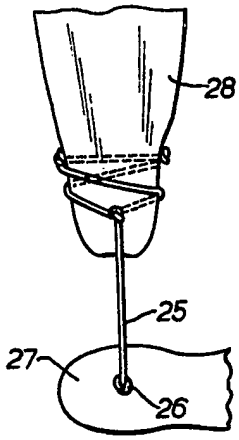

FIG. 5.

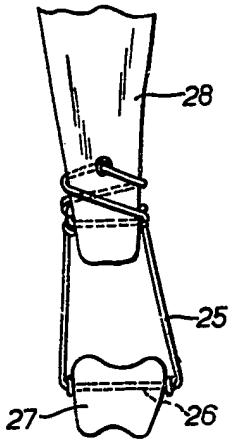

FIG. 6.